CLAIMS

What is claimed is:

1. A composition comprising a substantially integral bARE class protein.

- 2. The composition according to claim 1, wherein the composition comprises a stabilising agent.
- 3. The composition according to claim 2, wherein the stabilising agent is a charged amino acid or an analogue thereof.
- 4. The composition according to claim 3, wherein the stabilising agent is Arginine or Arginine Phospate.
- 5. The composition according to claim 4, wherein the Arginine or Arginine phosphate is present in an amount of from about 100mM to about 400mM.
- 6. The composition according to claim 2, wherein the composition comprises an uncharged agent or an analogue thereof.
- 7. The composition according to claim 6, wherein the composition comprises a zwitterionic agent.
- 8. The composition according to claim 7, wherein the zwitterionic agent is a zwitterionic detergent.
- 9. The composition according to claim 8, wherein the zwitterionic detergent is 3-(3-Cholamidopropyl)-dimethylammonio-1-propanesulfonate (CHAPS).
- 10. The composition according to claim 9, wherein the zwitterionic detergent is present in an amount of from about 0.05% to about 0.5% by weight per volume (w/v).

11. The composition according to claim 2, wherein the composition comprises a charged amino acid or analogue according to any one of claims 3-5 and an uncharged agent according to any one of claims 6-9.

- 12. The composition according to claim any one of claims 1-11, wherein the Integrity of the bARE class protein is determined with reference to an Integrity Ratio.
- 13. The composition according to any one of claims 1-12, wherein the bARE protein is an AB5 protein.
- 14. The composition according to claim 13, wherein the bARE protein is an LTK63 or LTK 72 protein.
- 15. A method of stabilising a bARE protein wherein the method comprises providing a bARE class protein and combining the bARE class protein with a stabilising agent.
- 16. The method according to claim 15, wherein the stabilising agent is a charged amino acid or an analogue thereof.
- 17. The method according to claim 16, wherein the stabilising agent is Arginine or Arginine Phosphate.
- 18. The method according to claim 17, wherein the Arginine or Arginine phosphate is present in an amount of from about 100mM to about 400mM.
- 19. The method according to claim 15, wherein the stabilising agent is an uncharged agent.
- 20. The method according to claim 19, wherein the uncharged agent is a zwitterionic agent.
- 21. The method according to claim 20, wherein the zwitterionic agent is a zwitterionic detergent.

22. The method according to claim 21, wherein the zwitterionic detergent is 3-(3-Cholamidopropyl)-dimethylammonio-1-propanesulfonate (CHAPS).

- 23. The method according to claim 22, wherein the zwitterionic detergent is present in an amount of from about 0.05% to about 0.5% by weight per volume (w/v).
- 24. The method according to claim 15, wherein the stabilising agent comprises a charged amino acid according to any one of claims 16-18 and an uncharged agent according to any one of claims 19-23.
- 25. The method according to any one of claims 15-24, wherein the stabilising of the bARE class protein is determined with reference to an Integrity Ratio.
- 26. The method according to any one of claims 15-25, wherein the bARE protein is an AB5 protein.
- 27. The method according to claim 26, wherein the AB5 protein is an LTK63 or LTK 72 protein.
- 28. A method of analysing a bARE class protein under non-dissociating conditions which differentiate between integral and dissociated bARE class proteins.
- 29. The method according to claim 28, wherein the method comprises a separation step on a charged polymeric separation material.
- 30. The method according to claim 29, wherein the polymeric separation material is a hydrogel monomer.
- 31. The method according to claim 30, wherein the hydrogel monomer is a hydroxylated polymethacrylate (HEMA) monomer.

32. The method according to claim 31, wherein the HEMA has a particle size of about 6 microns.

- 33. The method according to claim 31 or 32, wherein the HEMA has a porosity of about 250A.
- 34. A method of analysing a bARE class protein wherein the method comprises:
- (i) applying a bARE class protein to a charged polymeric separation material in an apparatus configured to resolve an integral bARE class protein from a dissociated bARE class protein;
- (ii) treating the separation material comprising the applied bARE class protein with an ionic buffer; and
- (iii) detecting one or more integral or dissociated bARE class proteins.
- 35. The method according to claim 34, wherein the separation material is as defined in any one of claims 30-33.
- 36. The method according to claim 34 or 35, wherein the ionic buffer is a physiologically acceptable buffer with a pH of from about 7.0 to about 8.0.
- 37. A method for identifying a bARE class protein stabilisation agent wherein the method comprises:
- (i) combining a bARE class protein with a candidate stabilising agent to form a bARE protein sample;
- (ii) applying the bARE protein sample to a charged polymeric separation material in an apparatus configured to resolve an integral bARE class protein from a dissociated bARE class protein;
- (iii) treating the separation material comprising the applied bARE class protein with an ionic buffer;
- (iv) detecting one or more integral or dissociated bARE class proteins; and

(v) determining whether the candidate stabilising agent is a bARE protein stabilising agent.

- 38. The method according to claim 37, wherein the method comprises calculating an Integrity Ratio for the bARE protein sample.
- 39. The method according to claim 38, wherein the method further comprises comparing the Integrity Ratio for the bARE protein sample with an Integrity Ratio for a control without a candidate stabilising agent.
- 40. A stabilising agent identified by the method of any one of claims 37-39.
- 41. The stabilising agent according to claim 40, which is a functional stabilising agent.
- 42. The stabilising agent according to claim 40, which is a physical stabilising agent.
- 43. An immunogenic composition comprising a composition according to any one of claims 1-14.
- 44. An immunogenic composition according to claim 43, wherein further comprising an adjuvant, wherein said adjuvant is not the bARE protein.
- 45. An immogenic composition according to claim 44, wherein the adjuvant is a mucosal adjuvant.
- 46. Use of a composition according to any one of claims 1-14 in the preparation of a medicament to prevent and/or treat an immune disorder.
- 47. A method of treating a mammal to prevent and/or treat an immune disorder comprising administering a composition according to any one of claims 43-45.
- 48. A method according to claim 47 wherein the mammal is a human.
- 49. Use of a charged agent to physically stabilise a bARE protein.
- 50. Use according to claim 49 wherein the charged agent is charged amino acid base.
- 51. Use according to claim 50 wherein the charged amino acid is a positively charged amino acid.

52. Use according to claim 51 wherein the positively charged amino acid is Arginine or Arginine Phospate or an analogue thereof.

- 53. Use of an uncharged agent or an analogue thereof to functionally stabilise a bARE protein.
- 54. Use according to claim 53, wherein the uncharged agent is zwitterionic agent.
- 55. Use according to claim 54 wherein the zwitterionic agent is a zwitterionic detergent.
- 56. Use according to claim 55 wherein the zwitterionic detergent is is 3-(3-Cholamidopropyl)-dimethylammonio-1-propanesulfonate (CHAPS).
- 57. Use of a combination of a charged agent and an uncharged agent or analogues thereof to stabilise a bARE protein.
- 58. Use according to claim 57 wherein the charged agent is defined in any one of claims 50-52 and the uncharged agent is defined in any one of claims 53-56.
- 59. Use according to any one of claims 49-58 wherein the bARE protein is an AB5 protein.
- 60. Use according to claim 60 wherein the AB5 protein is LTK63 or LTK72.